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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,550	11/24/2003	Ulrich Walter Drees	9/269	4564

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,550	DREES ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ferry et al. (US 6,147,095 IDS).

3. Ferry et al. teaches a method for improving the pharmacokinetics of tipranavir comprising administering a combination of therapeutical effective amount of tipranavir, and a therapeutical effective amount of ritonavir. See the claims. The method is particular useful for treatment of diseases caused by HIV, such as AIDS. See, particularly, col. 6, line 1 to col. 7, line 3. As to the limitation "highly treatment experienced HIV-infected patients," (see page 4, lines 22-24 for the definition), since HIV-infected patients can only be either "highly treatment experienced" (patients have been treated with 2 or more combination antiviral regimens before, page 4 of the specification), or "not highly treatment experienced" (patients have not been treated), and Ferry et al. do not particularly limited their method to either categories, one of ordinary skill in the art would have "AT ONCE ENVISAGED" the method of Ferry be useful for treatment of those HIV-infected patients with "highly treatment experienced."

Claim Rejections 35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferry et al. (US 6,147,095 IDS), in view of Loutfy et al.

6. Ferry et al. teaches a method for improving the pharmacokinetics of tipranavir comprising administering a combination of therapeutical effective amount of tipranavir, and a therapeutical effective amount of ritonavir. See the claims. The method is particular useful for treatment of diseases caused by HIV, such as AIDS. See, particularly, col. 6, line 1 to col. 7, line 3.

7. Ferry et al. do not teach expressly the treatment of "highly treatment experienced" HIV-infected patients, or the further incorporation of other anti-HIV drugs, capravirine, and/or "optimized background regimen comprising at least one nucleoside reverse transcriptase inhibitor." (see page 4 of the specification).

8. However, Ferry et al. reveals that it is well known in the art that to use combination of different types of antiviral drugs (cocktail) for treatment of HIV-infections. Currently three types of antiretroviral drugs are commonly used: nucleoside reverse transcriptase inhibitors (NRTI); non-nucleoside reverse transcriptase inhibitors (NNRTI), and protease inhibitors (PI). See, particularly, col. 2, line 63 to col. 3, line 35. Further, Loutfy et al. disclosed that it is a common practice in the art of HIV-infection treatment to use new developed antiretroviral drugs for those

patients who fails to response to known cocktail treatments. See, particularly, pages 81, page 84, the right column. Loutfy et al. also disclosed that tipranavir (PI) and capravirine (NNRTI) are two of the new antiretroviral drugs. See, page 86, particularly table 2. Loutfy et al. further disclosed that the employment of genotyping and phenotyping for optimization of a cocktail anti-HIV regimen is known in the art. See, page 85.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the combination of tipranavir and ritonavir disclosed by Ferry for treatment of those HIV-infected patients who fails to response effectively to other combination therapy, particularly in combination with other new antiretroviral drugs, such as capravirine to form a new cocktail regimen, because new drug is generally effective against those strain resistant to current drugs. Note Tipranavir is particularly known for that (see page 86 in Loutfy). Further, optimization of the drug cocktail based on genotyping and/or phenotyping would have been obvious to one of ordinary skill in the art since such technique is known in the art. Incorporation of another different type of drug (NRTI) would have been obvious to one of ordinary skill in the art because it is known in the art to use different types of drugs in a cocktail combination.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617